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Date: November 30, 2004

By

Mary Sims

Signature of person depositing U.S. Mail

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT

Applicants: WANG, Hsiang, et al.

Docket No.: 39524.9800

Serial No.: 10/811,757

Filed: March 29, 2004

TITLE: PHARMACEUTICAL COMPOSITION FOR
PROPHYLAXIS OR TREATMENT OF
OSTEOPOROSIS, AND METHOD TO PREPARE
THE SAME

Group Art Unit: 1614

Confirmation No.: 2850

**INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§1.97-1.98**

Mail Stop: Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §§1.97-1.98, the references listed and identified on the attached PTO/SB/08a form are being submitted herewith for consideration by the Examiner.

The references are being cited only in the interest of candor and without any admission that they constitute statutory prior art or contain matters which anticipate the invention or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art.

For each item listed on the enclosed copy of Form PTO/SB/08a that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is set forth below:

China Patent No. 1080537 - The product for prevention and caring of osteoporosis contains the extract of cnidium fruit which has the actions of regarding the substance of bone

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from further loss and promoting to form new bone. It is an ideal medicament at present for prevention and curing of osteoporosis and can be made into medicines or health care products.

China Patent No. 1099632 - The preparation method firstly decocts the mixture of such traditional Chinese medicinal herbs into medicinal liquid as desert cistanche, longspur epimedium, tuber of multiflower knotweed, fruit of Chinese magnoliavine, seed of Chinese dodder, and cnidium fruit; said medicinal liquid is mixed with the liquid of male silk moth soaked by spirit and the alcohol treated squeezed juice of rhamnoide, at last it is finished by adding saponin of the stem and leaf of ginseng, sodium benzoate and cane sugar. The invented product features containing multiple kinds of vitamins, anti-senility, obvious immunoenhancemental function, tonifying the kidney and improving the sexual function.

China Patent No. 1121810 - The Chinese-medicinal compound preparation for curing osteoporosis with high curative effect, low cost and no toxicity is prepared from cnidium fruit, epimedium and pearl powder. The 10 prescriptions are disclosed for curing osteoporosis caused by different reasons such as primary one, menopause, senility, hypercorticism, hyper thyroidism, diabetes mellitus, etc.

China Patent No. 1177488 - The reference discloses a Chinese medicine preparation for curing prospermia-Yangang Yuye oral liquor. It is made from 12 Chinese medicinal materials of cordyceps, saffron, musk, sumac gallnut, cuscuta seed, cnidium seed, phellodendron bark, lycium berry, euryale seed, walnut kernel, black soybean and lotus seed, extracting their effective components by using scientific method and concentrating them to obtain the invented product. Said invention has no side effect or dependence and has good therapeutic effect.

China Patent No. 1223296 - The reference discloses a production method of kidney-boosting tonic liquor, belonging to the Chinese medicine health-care liquor. Said kidney-boosting tonic liquor is made up by using 19 Chinese medicinal materials of (wt%) ginseng 0.47-0.58, velvet deerhorn, aquilaria wood 1.18-1.45 each, cordyceps 4.21-5.26, cooked rehmannia 11.84-14.47, rock sugar 9.20-11.84, cistanche stem, cuscuta seed, polygala root, eucommia bark, cnidium seed, dipsacus root, schisandra berry and Chinese angelica root 2.89-3.42 each, sea horse 2.11-2.63, tortoise plastron 25.78-26.84, carthamus flower and

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corydalis tuber 2.50-2.76 each and lycium berry 8.95-9.46 as raw materials, using low-alcohol grain liquor containing 38-40 percent alcohol as solvent and adopting a certain preparation process. Said tonic liquor possesses the functions of supplementing kidney, strengthening yang, nourishing liver, brightening eyes and building up body, etc.

Korea Patent No. 2000066767 - A tea containing medicinal mushroom such as *Lycium chinense* MILL., *Cynanchum wilfordii*, *Eucommiae cortex*, *Cuscuta chinensis* LAM., *Rubus chingii* Hu., *Cnidium monnieri* L., *Poria cocos* WOLF is provided, which is able to improve immune system. The preparation method comprises removing foreign materials from *Lycium chinensis* LAM., *Rubus chingii* Hu., *Cnidium monnieri* L., *Poria cocos* WOLF, followed by washing and drying; heating in an extractor for 3 h after gauging them accurately; mixing the exts. with fructose in a shaker; and packaging after sterilization. The obtained tea composition comprises 3.98% of *Cynanchum wilfordii*, 3.98% of *Cuscuta chinensis* LAM., 2.08% of *Lycium chinense* MILL., 2.08% of *Rubus chingii* Hu., 2.08% of *Cnidium monnieri* L., 4.16% of *Eucommia ulmoides* OLIV., 6.6% of fructose, and 72.96% of distilled water.

China Patent No. 1277848 - The present invention relates to a traditional Chinese medicinal preparation for treating osteoporosis and is characterized by that it is composed of (weight portion): prepared rehmannia root (10-90), cinnamon bark (3-27), fructus corni (6-60), fructus psoraleae (6-70), cortex eucommiae (6-60), semen cuscatae (6-60), yam (5-45), rhizoma alismatis (3-27), radix morindae officinalis (10-90), and poria (5-45).

China Patent No. 1368151 - The "Hailong Hajie" compns. (such as pills, tablets, suppositories, granules, films and capsules) with high bioavailability comprise nanoparticles Syngnathus 30-60, Gecko 0.2-2, Ginseng 2-8, goat penis 2-8, goat kidney 2-8, Scutellaria 2-8, roasted Rehmannia glutinosa 2-5, *Cuscuta chinensis* 2-6, *Polygonum multiflorum* 2-6, *Rehmannia glutinosa* 2-6, "Chenpi" (pericarpium citri reticulatae) 2-6, *Angelica* 1-5, *Astragalus* 3-8, actinolite 1-5, *Nelumbo nucifera* tassel 1-3, *Clycyrrhiza* 1-3, *ligusticum wallichii* 1-3, *Alisma* 1-3, "Suoyang" (*herba cynomorii*) 1-3, *Amomum cardamomum* 1-3, *Aquilaria agallocha* 1-3, deer antler 1-3, *Lycium barbarum* seed 1-3, *Cistanche deserticola* 0.5-2, *Epimedium grandiflorum* 1-3, *Cassia* 1-3, *Allium odorum* seed 1-3, *Cnidium monnieri* 1-3, and *Xanthoxylum*

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bungei 0.1-4 parts. All of the above nanoparticles are manufactured by soaking the natural occurrences with solvents at 30-60° for 3-72 h, mixing the product with volatile oils, and spray drying at 30-60° and 0-0.05 MPa with the jet rate of 300-900 m sl.

China Patent No. 1368230 - The "Cane Gongbu" nanometer prepsns. (such as pill, tablet, suppository, granule, film, capsule, etc.) with high bioavailability are composed of male silkworm moth 350-700, ginseng 35-80, roasted Rehmannia glutinosa 150-400, Atractylodes macrocephala 150-400, Angelica 120-300, Lycium barbarum seed 120-300, Psoralea corylifolia 120-300, Cuscuta chinensis 80-180, Cnidium monnieri seed 70-180, Curculigo orchioides 80-180, Cistanche deserticola 80-180, and Epimedium grandiflorum 80-180 part. All of the above Chinese medicine are nanometer slices, and prepared by extracting with solvent at 30-60° for 1-10 h under microwave radiation, concentrating at 30-60° for 3-72 h under collecting volatile oil, mixing the extract with the volatile oil, and spray drying at 30-60° and 0-0.05 MPa with the jet rate of 300-900 m s-l.

China Patent No. 1457822 - The medicine is prepared with lettuce seed, eaglewood, rice, frankincense, white atractylodes rhizome and dodder seed as raw materials. Through traditional Chinese medicine preparing process, the medicine in troche, soft capsule, granule, decoction or bolus is prepared. The medicine purportedly has unique recipe and obvious fracture and osteoporosis treating effect.

Each item of information contained in this Information Disclosure Statement is being disclosed prior to the issuance of the first Office Action on the merits pursuant to 37 C.F.R. §1.97(b)(3); therefore, no filing fee is required. If the Applicant has overlooked any fees, and/or it is determined that this IDS has been filed under the wrong rule, the United States Patent and Trademark Office is requested to consider this IDS under the proper rule (with a petition if necessary), and the Commissioner is hereby authorized to debit Deposit Account No. 19-2814 for the same. **A duplicate copy of this page of the Information Disclosure Statement is enclosed for this purpose. This statement does not authorize the payment of the issue fee.**

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If there are any questions concerning this IDS, the Examiner is requested to contact the undersigned.

Respectfully submitted,

DATE: November 30, 2004

By:



Cynthia L. Pillote (Reg. No. 42,999)

Enclosures: PTO/SB/08a
Copy of foreign citations

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/811,757
				Filing Date	March 29, 2004
				First Named Inventor	WANG, Hsiang, et al.
				Art Unit	1614
				Examiner Name	TBA
				Attorney Docket Number	39524.9800
Sheet	1	of	2		

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind ⁵ (if known)				
	A	CN	CN1080537		01/12/1994	Médecine Tech		
	B	CN	CN1099632		03/08/1995	Chifeng Pharm		
	C	GB	GB 2 282 966		04/26/1995	Jiang		
	D	CN	CN1121810		05/08/1996	Medicinal Sci		
	E	CN	CN1177488		04/01/1998	Wang Yongcheng		
	F	CN	CN1223296		07/21/1999	Liu Guangsheng		
	G	KR	KR2000066767		11/15/2000	In Chon Forestry		
	H	CN	CN1277848		12/27/2000	Radiation Med		
	I	CN	CN1368151		09/11/2002	Peop. Rep. China		
	J	CN	CN1368230		09/11/2002	Peop. Rep. China		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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